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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,569	07/17/2000	Petrus W. Roelvink	204133	7936

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/24/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/617,569

Applicant(s)

ROELVINK ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-19,21-32,40 and 43-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-19,21-32,40 and 43-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

In paper no. 20, applicant amended claims 21, 22, 28, 29 and added new claims 52-54.

Claims 1-6, 8-19, 21-32, 40 and 43-54 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-17, 19, 21-24, 26-31, 40, 43, 44, 46, 48, 50 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al. (US 5,846,782) and Kikuchi et al. (Human Gene Therapy. 1999; 10: 1375-1387) for reasons of record. (Since newly presented claims 52-54 encompass subject matter previously presented, these claims are grouped with the rejection of record.)

Claims 18, 25, 32 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al. and Kikuchi et al. as applied to claims 1-6, 8-17, 19, 21-24, 26-31, 40, 43, 44, 46, 48 and 50 above, and further in view of Janeway et al. (1997. Immunobiology. 3rd edition. Garland Publishing Inc. Page 7:27) for reasons of record.

Claims 47, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al. and Kikuchi et al. as applied to claims 1-6, 8-17, 19, 21-24, 26-31, 40, 43, 44, 46, 48 and 50 above, and further in view of Ashkar et al. (Science. February 4, 2000; 287: 861-864) for reasons of record.

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Applicant argues that neither the Wickham nor the Kikuchi reference teach or suggest a non-native antigen displayed on the virion surface. Applicant asserts that the teaching of Wickham stating that adenoviruses can express a wide number of recombinant genes is a well-known fact in the art, but does not suggest displaying non-native antigens on the surface of the virion. Applicant also argues that Wickham does not identify any of the passenger genes as antigens, which the claims require. Applicant points out that Kikuchi reference does not teach the CD40 ligand expressed as part of the adenovirus capsid.

Applicant's arguments have been fully considered, but are found unpersuasive.

Wickham et al. teach a recombinant adenovirus that has a chimeric adenovirus fiber protein comprising an RGD motif, see claims 1-3, 8, 19, 20, and 24; column 6, lines 28-53 and column 9, lines 29-45. This motif is present to retarget the native adenovirus, see column 35, lines 34-43. While it is apparent that the adenovirus of Kikuchi does not express the CD40 ligand on the surface, the reference is not required to teach this limitation because the reference provides motivation for the ordinary artisan to express the ligand on the adenovirus of Wickham. As stated in the previous Office action, one of ordinary skill in the art at the time the invention was made would have been motivated to express a CD-40 ligand (taught by Kikuchi) on the adenovirus of Wickham et al. to induce antigen-presenting cells to present antigens to the cellular immune system. Wickham teaches how to express different nonnative amino acid sequences on the surface of adenoviruses and Kikuchi provides motivation to express CD-40 on the surface of the adenovirus.

The CD-40 ligand taught by Kikuchi expressed on the surface of the adenovirus of Wickham would render the recombinant adenovirus specific to antigen-presenting cells (APCs),

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see the teachings of Wickham et al. for altering viral tropism with non-native sequences expressed on the surface. Although neither reference expressly teaches expressing a second antigen on the adenovirus surface, one of ordinary skill in the art at the time the invention was made would have been motivated to express an antigen on the surface of the adenovirus to induce a specific immune response in APCs against a particular antigen.

With respect to the passenger genes taught by Wickham et al., these genes are taught to elicit a strong immune response and can be any gene, see column 14, lines 37-59, column 19, lines 19-38, and column 20, lines 12-26. An antigen, defined by Cruse et al. (Illustrated Dictionary of Immunology. Boca Raton: CRC Press; 1995, page 21) is “a substance that reacts with the products of an immune response stimulated by a specific immunogen”. That is, an antigen elicits an immune response, as do the passenger genes of Wickham. The characteristics describing the passenger genes encompass antigens. Therefore, Wickham teaches an adenovirus comprising at least one nonnative antigen.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley


JAMES HOUSEL 9/22/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600